

REMARKS

Reconsideration of the present application in view of the above amendments and following remarks is respectfully requested. Claims 1-6, 8, 9, 11-57, 66-120, 134-182, 201-208, 220-222, 230-232, 239-242, 247-253, 255-258, 262-266, 271, 273-275, 278-281, 286, 288-291, 294, 298, 300-303, 309, 311-313, 321-323, 328, 330, 331, 336, 338-341, 346-348, and 353-372 were pending. As set forth above, Applicants have hereby canceled claims 84-120 without prejudice to the filing of any divisional, continuation, or continuation-in-part application thereon. Furthermore, Applicants have hereby amended claims 15, 75, 83, 361 and 367 to more clearly define the subject matter encompassed by the Applicants' invention, and amended claims 8, 11, 13, 14, 18, 360, 363, 365, 366, 369, 370 and 372 to merely correct obvious inadvertent typographical errors or to correct claim dependencies. Applicants hereby submit new claims 373-375, support for which may be found in the application and claims as originally filed. No new matter has been added. Accordingly, claims 1-6, 8, 9, 11-57, 66-83, 134-182, 201-208, 220-222, 230-232, 239-242, 247-253, 255-258, 262-266, 271, 273-275, 278-281, 286, 288-291, 294, 298, 300-303, 309, 311-313, 321-323, 328, 330, 331, 336, 338-341, 346-348, and 353-375 are currently pending.

CLAIMS OBJECTION

In the Office Action dated July 8, 2003, claims 8, 11, 13, and 14 were objected to for depending from cancelled claim 7. Applicants wish to thank the Examiner for identifying this inadvertent oversight and submit that claims 8, 11, 13 and 14 have been amended to properly depend from claim 1. Accordingly, Applicants respectfully submit that this objection has been obviated.

REJECTION UNDER 35 U.S.C. §112, SECOND PARAGRAPH

In the Office Action, claims 87 and 89 were rejected under 35 U.S.C. §112, second paragraph, as indefinite.

Applicants respectfully submit that this ground of rejection has been rendered moot because claims 87 and 89 have been hereby cancelled without prejudice, as set forth above. Accordingly, Applicants respectfully request that this ground of rejection be withdrawn.

REJECTIONS UNDER 35 U.S.C. § 103(a)

(1) In the Office Action, claims 1, 5, 12, 15, 18-20, 57, 66-77, 92, 113, 182, 201, 207, 208, 220, 221, 222, 230 and 358-366 were rejected under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 6,080,099 (Slater *et al.*) in view of U.S. Patent No. 5,651,986 (Brem *et al.*). In particular, it is alleged that it would have been obvious for a person having ordinary skill in the art to modify the system and method of Slater *et al.* to include the use of biodegradable polymer with a cell-cycle inhibitor, as taught by Brem *et al.*, to provide a means of supplying localized radiation and chemotherapy at a tumor site.

Applicants respectfully traverse this ground of rejection and submit that Slater *et al.* and Brem *et al.*, taken alone or in combination, fail to teach or suggest the claimed invention. Briefly, where claimed subject matter has been rejected as obvious in view of a combination of prior art references, a proper analysis under §103 requires, *inter alia*, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success. *In re Vaeck*, 947 F.2d 488, 20 USPQ.2d 1438 (Fed. Cir. 1991).

In the instant case, the cited references meet neither of these criteria. In particular, the present invention is directed, in pertinent part, to a therapeutic device comprising a device, which locally administers radiation, and a spacer, wherein the spacer includes a polymer and a cell-cycle inhibitor. Slater *et al.* describe a radioactive seed that consists of a capsule containing a radioactive isotope, and describe linking of such seeds together with a bioabsorbable spacer. However, Slater *et al.* do not define in any way what constitutes a "bioabsorbable spacer" (*i.e.*, there is no mention of a polymer) and, therefore, also fail to teach or suggest a spacer that comprises a polymer. Applicants respectfully submit that Slater *et al.* fail to enable the use of a "bioabsorbable spacer" because no material is described as suitable for such

a purpose. Moreover, Slater *et al.* are concededly silent with regard to the use of cell-cycle inhibitors, much less a spacer that includes a polymer and a cell-cycle inhibitor. Therefore, Slater *et al.* fail to teach or suggest a therapeutic device according to the instant invention.

Furthermore, the addition of Brem *et al.* does not remedy the deficiencies of Slater *et al.* Brem *et al.* disclose the use of polymer compositions containing chemotherapeutic agents for delivery to solid tumors. However, Brem *et al.* are silent with regard to the use of a device that locally administers radiation, much less a device that locally administers radiation in combination with a spacer that includes a cell-cycle inhibitor. Furthermore, Brem *et al.* do not teach or suggest the use of a polymer as a spacer. Hence, even assuming *arguendo*, a person having ordinary skill in the art were to combine Slater *et al.* and Brem *et al.*, such a person would have had no reasonable expectation of success because there is no teaching or suggestion that the Brem *et al.* polymer would function as a "bioabsorbable spacer" as described by Slater *et al.* Applicants respectfully submit that the mere fact that the teachings of the prior art *can* be combined or modified, or that a person having ordinary skill in the art is *capable* of combining or modifying the teachings of the prior art, does not make the resultant combination *prima facie* obvious, as the prior art must also suggest the desirability of the combination (*see, e.g., In re Mills*, 16 U.S.P.Q.2d 1430, Fed. Cir. 1990; *In re Fritch*, 23 U.S.P.Q.2d 1780, Fed. Cir. 1992). Hence, Slater *et al.* and Brem *et al.*, taken alone or in combination, fail to teach or suggest a device that combines radiation and a cell-cycle inhibitor according to the instant invention.

In sum, Applicants respectfully submit that a *prima facie* case of obviousness has not been set forth in the Office Action. In particular, no evidence has been provided that, at the time of filing the instant application, a person having ordinary skill in the art would have been motivated to arrive at the claimed invention with a reasonable expectation of success, given the disclosures of the cited references. Accordingly, Applicants respectfully submit that the instant claims satisfy the requirements of 35 U.S.C. § 103(a) and, therefore, request that this rejection be withdrawn.

(2) In the Office Action, claims 9, 11, 83-86, 90, 91 and 114-120 were rejected under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 6,080,099 (Slater *et al.*) and U.S. Patent No. 5,651,986 (Brem *et al.*) in view of U.S. Patent No. 6,248,057 (Mavity *et al.*).

More specifically, it is alleged that it would have been obvious for a person having ordinary skill in the art to modify the device and method of Slater *et al.* and Brem *et al.* to include the use of a coating on the radioactive seed for delivering the cell-cycle inhibitor, as taught by Mavity *et al.*, to provide a means of delivering radiation and a chemotherapeutic agent to the same spot rather than have a chemotherapeutic agent adjacent to a radioactive seed.

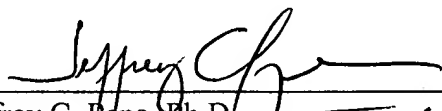
Applicants respectfully submit that this ground of rejection has been rendered moot because the claims relevant to this rejection (claims 83-86, 90, 91 and 114-120) have been hereby cancelled without prejudice and without acquiescing or agreeing with the instant invention. Accordingly, Applicants respectfully request that this rejection be withdrawn.

The Commissioner is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

All of the pending claims in the application are now clearly allowable. Favorable consideration and a Notice of Allowance are earnestly solicited. The Examiner is urged to contact the undersigned attorney if there are any questions prior to allowance of this matter.

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